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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,438	04/13/2001	Paul G. Alchas	P-4498P2	2953

7590

04/20/2004

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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/20/2004

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,438

Applicant(s)

ALCHAS ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,17,18,24-27,30-35,41,42,48-58,61-65 and 71-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,17,18,24-30,41,42,48-55,61,64,65 and 71-73 is/are rejected.
- 7) ☒ Claim(s) 5-10,31-35,56-58,62 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

The drawing objection is maintained since applicant has failed to address the issue.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plane within about 15 degrees or 5 degrees must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 17-18, 26-29, 41-42, 50, 51, 53-55, 61, 64, 65, 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinicke (U.S. Patent No. 4,834,704).

Reinicke discloses an intradermal needle assembly comprising a hub portion , a needle cannula (4) a limiter portion (2) having a generally flat skin engaging surface

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(2b) extending in a plane generally perpendicular to the axis of the needle. The needle cannula and limiter portion is non-movable with respect to each other. See figure 5. Reinicke discloses the forward tip to extend beyond the skin engaging surface (2b) a distance approximately 0.5 mm to 3.0 mm See col. 4, line 3. the functional limitations are met since the device of Reinicke can perform the function. The plane generally perpendicular to the needle axis is within about 15 or 5 degrees. The abutment is considered to be shown in figure 5. the Examiner has given the broadest interpretation of the claim language. The hub portion is considered the 2c or 2f.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-25, 48-49, 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinicke in view of Reich (U.S. Patent No. 5,672,883).

See above Reinicke discloses the invention as substantially claimed. However, Reinicke is silent to a forward and rearward cap that encloses the needle assembly there between. Reich teaches a container for storing needle assemblies with a forward and rearward cap for safe handling and transporting of needle assemblies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to

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modify the assembly of Reinicke with a rearward and forward cap as taught by Reich for safe handling of needle assemblies under government regulations.

Claims 4,30, 52 are rejected under 35 U.S.C. 103 as being unpatentable over Reinicke (U.S. Patent No. 4834704) .

Reinicke discloses the invention substantially as claimed. See above. However, Reinicke does not disclose the hub portion and the limiter portion formed as separate pieces. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hub and the limiter portion as separate pieces in as a mere design choice in manufacturing. The mere fact that a given structure is integral does not preclude its consisting of various elements. In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Allowable Subject Matter

Claims 5-10, 31-35,56-58,62-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 02/04/04 have been fully considered but they are not persuasive. Applicant's arguments are not persuasive since applicant is arguing the intended use. Applicant is reminded that the claims are directed to a device. Further,

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applicant is correct in stating that the Reinicke patent discloses a broader range. As such, the broader range encompasses the range of applicant's claimed limitation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

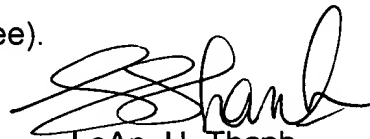
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
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